$ Fee

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPELLANTS:	Brand et al.	CONFIRMATION NO. 5055
SERIAL NO.:	09/763,387	GROUP ART UNIT: 3762
FILED:	April 18, 2001	EXAMINER: Frances Oropeza
TITLE:	"PACEMAKER HOUSING WITH LEAD CONNECTION ASSEMBLY"	

MAIL STOP APPEAL BRIEF-PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPELLANTS' APPEAL BRIEF

S I R:

In accordance with the provisions of 37 C.F.R. §1.192, Appellants herewith submit their brief in support of the appeal of the above-referenced application.

REAL PARTY IN INTEREST:

The real party in interest is the assignee of the present application, ST. JUDE MEDICAL AB, a Swedish corporation.

RELATED APPEALS AND INTERFERENCES:

There are no related appeals and no related interferences.

STATUS OF CLAIMS:

The present application is a PCT application for which, when entering into the National Examination Phase in the United States, the then-pending PCT claims were canceled, and claims 7-17 were submitted. Of those claims, 7-13, 16 and 17 stand rejected, and are the subject of this appeal. Claims 14 and 15 have been objected to, and were stated to be allowable if rewritten in independent form, and therefore are not at issue in this appeal.

STATUS OF AMENDMENTS:

No Amendment was filed following the final rejection.

SUMMARY OF THE INVENTION:

All page and line numberings refer to the substitute specification, filed with the original application papers for entry into the examination phase in the United States.

Fig 2 illustrates a lead 15 comprising a proximal connecting plug 10 and a distal, transveneous, intracardial electrode 16 as well as an attachment means 17 for suturing the proximal end of the lead in the body of the patient. (p.4, l.17-21) The connecting plug 10 is designed to be received in the socket 3 and the end thereof is provided with a longitudinally projecting contact pin 11 as well as a cylindrical body 17 provided with sealing rings 12, 13, 14 intended to engage and seal against the corresponding inner cylindrical surface of the female socket 3. (p.4, l.21-26) The shape of the pin 11 corresponds to the shape of the bore 7. (p.4, l.26 - p.5, l.1) When the plug 10 is inserted into the socket 3 the pin 11 engages the contact surface 4 and the set-screw in the bore 6 can be tightened against the pin 11 in order to securely lock the plug 10 in the socket 3. (p.5, l.1-5) The complexities involved in holding the bores, contact surfaces and threads in position and keeping them open and free from the molding material during the molding process are evident. (p.5, l.5-9)

Figs 3 - 5 show a preferred embodiment of the invention comprising a tubular member 20. The reference numerals have not been repeated throughout all figures. (p.5, l.14-16)

The tubular member 20 is a tube 21 with two open ends 22, 23. Each end is to be welded into a respective opening in the pacer housing. The tube 21 is made of

the same metal as the pacer housing, in this case titanium. (p.5, l.17-20) The mid-section of the tube 21 is provided with two relatively small lateral openings 24, 25. The openings 24, 25 are sealed by means of a ceramic plug 26 fitting snugly in the tube and soldered with gold against the inside of the tube 21. (p.5, l.20-24) Two contact rings 27, 28 in the plug 26 overlap the lateral openings 24, 25. (p.5, l.20-25)

It should be noted that the size of the openings 24, 25 which are necessary to allow the bonding of the leads to the parts of the contact rings accessible through the openings 24, 25 and 31, 32 is small, in relation to the entire circumference and to the length of the tube 21. The openings thus do not affect the structural integrity of the tube 21. The contact rings 27, 28 moreover overlap the openings and are bonded thereto by means of the intermediate layer of ceramics, in this way strengthening the area in which said openings are located. (p.6, l. 4-13)

The ceramic plug is provided with an interior bore 10 corresponding to the shape of the male connector in the same way as the molded prior art female connector described above and thus includes interior sealing surfaces 52, 53 for engagement with the sealing rings on the male connector. (p.7, l.13-17)

A part 30, 31 of the inside of the contact rings is not covered with the ceramic material. In this way two inner circumferential grooves are obtained in the inner bore of the ceramic plug. The bottom of the grooves consists of the metal in the contact rings. (p.7, l. 18-22) Two openings 32, 33 are also provided in the outer surface of the ceramic plug that may be made to coincide with the lateral openings 24, 25 in the tube wall. These openings give access to the contact rings 27, 28 when the ceramic plug has been mounted correctly in the tube 21. (p7, l.22-26)

Thus, when the ceramic plug 26 has been soldered or bonded into place, the openings 24, 25 will be completely sealed by the plug 26 although allowing electrical connection to the interior of the tube 21 via the contact rings 27, 28. (p.8, l.1-4)

To this extent the tubular member can be manufactured in advance as desired. (p.8, l.5-6)

Both ends of the prefabricated tube 21 can be welded to the pacer housing and the housing parts can be welded together after the connection of interior leads from the interior electronics to the contact rings 27, 28, should this be desired. (p.8, l.7-11)

Fig 3 shows the main component parts of the tubular member, the tube 21 with openings 24, 25, the ceramic plug 26, a fixation part 40 and two circular spring contacts 57, 58. (p.8, l.21-23)

The fixation part 40, shown in more detail in Fig 4, has a hollow cylindrical part 41 fitting into the end of the tube 21. The inner end of the cylindrical part 41 is provided with an interior flange 42 with an inner conical surface 43. (p.9, l.1-7) The locking device further comprises a resilient locking ring 44 located adjacent the flange 42. One side of the ring has a conical surface 45 that is complementary to the conical surface 43. (p9, l.7-10) The other side of the ring also has a conical surface 46 that is complementary to a conical surface 47 on a plug 48 provided with exterior threads 49 fitting into interior threads 50 on the inside of the cylindrical part 41. (p9, l.10-14) The outside of the plug 48 is provided with an O-ring 51 that is located in a peripheral groove 52 and sealingly engages the inside of the cylindrical part 41. When the plug 48 is screwed into the cylindrical part 41, the resilient ring 44 will be forced inwards into contact with the contact pin of the male connector part by means

of the interaction of the different conical surfaces, thus locking the contact pin inside the tube. (p.9, l. 14-21)

Fig 4 shows the tube 21 with all component parts mounted. (p.10, l. 8)

Fig 5 shows how the tube has been mounted in a pacer housing 60 and welded to openings 61, 62 in the openings via flanges located on the outside of the tube ends. (p.10, l.9-11) Fig 5 also shows a male connector plug 110 inserted in the tubular member. (p.10, l.11-13) The plug has a contact pin 111, a contact surface 118 and four sealing rings 112, 113, 114, 117. The resilient ring 44 grips the pin 111 and the sealing rings 112 - 114, 117 are in engagement with the interior sealing surfaces 52, 53. (p.10, l.13-16)

Since the tube after the welding operation in principle forms an integral, load-carrying part of the pacer housing, a high degree of tightness and integrity is obtained. The tube will ensure a high strength and a high durability of the connective part, while the ceramic plug will ensure a high degree of tightness in view of the large contact area between ceramic plug and tube that can used for soldering, i.e. sealing. (p.11, l.19-26)

ISSUE:

The following issues are presented for review:

Whether the subject matter of claims 7-13 would have been obvious to a person of ordinary skill in the field of pacemaker design under the provisions of 35 U.S.C. §103(a), based on the teachings of United States Patent No. 5,383,913 (Schiff) in view of United States Patent No. 6,029,089 (Hawkins et al.); and

Whether the subject matter of claims 16 and 17 would have been obvious to a person of ordinary skill in the field of pacemaker design under the provisions of 35

U.S.C. §103(a), based on the teachings of Schiff and Hawkins et al., further in view of United States Patent No. 4,784,141 (Peers-Trevarton).

GROUPING OF CLAIMS:

The patentability of claims 7-13 stands or falls together. The patentability of claims 16 and 17 stands or falls together, but does not stand or fall together with the patentability of claims 7-13. Separate arguments are provided for the patentability of claims 7-13 and for the patentability of claims 16 and 17.

ARGUMENT:

In the Final Action claims 7-13 were rejected under 35 U.S.C. §103(a) as being unpatentable over Schiff in view of Hawkins et al. With regard to independent claim 7, the Examiner acknowledged that the Schiff reference does not disclose that the housing is metallic. The Examiner relied on the Hawkins et al. reference as teaching an implantable device component assembly having a metallic housing with a barrel for receiving a connector that is welded or bonded to the housing, in order to secure the barrel assembly in the device. The Examiner stated it would have been obvious to a person of ordinary skill in the art to use a metallic housing and bonding or welding in the Schiff system, in order to simplify the device housing by replacing the cast epoxy connector with a metallic housing, and using a weld bond to provide firm attachment of the barrel.

Appellants' arguments in support of the patentability of claims 7-13 are as follows.

Conventionally the so-called "header" or electrode lead-receiving portion of an implantable stimulation device has been made of plastic or silicone, with metallic components embedded therein and electrical connections between those metallic

components and the circuitry contained in the metallic portion of the stimulator housing. The stimulator disclosed in the Schiff reference is an example of such a conventional arrangement.

Appellants acknowledge in the present specification that it is known to make the stimulator housing completely of metal, however, conventionally this has proven to be the exception rather than the rule, because of many difficulties associated with the use of a completely metallic housing, not the least of which are insulation problems, and the issue of how to attach or mount the female connector portion in such a metallic housing.

Appellants therefore respectfully submit that a person seeking to design an implantable stimulator with a metallic housing, or at least a metallic header, would not start with a conventional arrangement of the type described in Schiff, having a silicone or plastic header, and try to modify it in order to overcome the aforementioned problems which are exclusively related to stimulators having a metallic housing or a metallic header. In fact, the Hawkins et al. reference is evidence of the non-obviousness of the subject matter if claims 7-13, rather than the obviousness thereof. The Examiner has focused on the Hawkins et al. reference because it discloses using a weld bond to provide a firm attachment of the barrel to the housing, however, independent claim 7 of the present application requires the use of a metallic *tubular* member having opposite first and second tube ends that are respectively disposed in opposite first and second openings of first and second walls of the metallic housing, and further explicitly states that the tubular member is substantially *continuous* between the first tube end and the second tube end. This is best seen in Figures 4 and 5 of the present application wherein it can be seen that

the element 21 is a "true" tube. Except for the openings 24 and 25. the tube 21 is continuous between the opposite ends that are connected to the metallic housing. This inventive solution not only overcomes the aforementioned insulation problems, but allows attachment to the metallic housing by means of welding or bonding.

The structure disclosed in the Hawkins et al. reference, although making use of welding or bonding, *is not a tube.* As can be seen in Figure 5 of the Hawkins et al. reference, for example, the female socket is composed of a number of successive parts that must be joined together, many of which, such as elements 58 and 60, are insulating. There is no substantially continuous tube disclosed anywhere in the Hawkins et al. reference. There is not even an embodiment in the Hawkins et al. reference that makes use of openings in opposite walls of the metallic housing or header so that the use of a substantially continuous tube would even be meaningful.

This is evidence of the difficulty of arriving at a simplified and operable structure for the female connector socket in the context of the use of a metallic housing or header. It is true that the Schiff reference, as shown in Figure 3, illustrates a structure which could be argued to be a substantially continuous tube, however, it must be remembered that this is in the context of a plastic or silicone header, and the insulating problems which would arise if the structure shown in Figure 3 of the Schiff reference were attempted to be used in a metallic housing or header have already been extensively discussed. Those insulation problems would not disappear if one simply substituted the end portions disclosed in the Hawkins et al. reference for the end portions of the tubular structure shown in Figure 3 of the Schiff reference. This is evidence of the thinking of those of ordinary skill in the art that, if a metallic housing or metallic header is to be used, the assembly for the

female socket should not be a substantially continuous tube, but should be composed of separate components joined together, some of which are insulators. This is why one cannot simply begin with a structure intended for use in a silicone or plastic header, and make arbitrary changes therein in accordance with teachings related to female socket assemblies for use with a metallic header, and assume that the structure used in the plastic or silicone header can otherwise remain unchanged.

The substantially continuous tube disclosed in the Schiff reference can be used only because the header is composed of silicone or plastic. Simply because the Hawkins et al. reference shows how one end of a female socket assembly can be bonded to a metallic housing or header does not mean that, if the Hawkins et al. assembly were somehow embodied in the Schiff assembly, the housing in the Schiff reference could then arbitrarily be made metallic. The aforementioned insulation problem still would not be overcome in such a combination, and there is no teaching in any of the references of record as to how those problems can be solved while still making use of a substantially continuous tubular member in the socket assembly.

The subject matter of claim 7, therefore, would not have been obvious to a person of ordinary skill in the art based on the teachings of Schiff and Hawkins et al., nor would the subject matter of claims 8-13 depending therefrom.

Claims 16 and 17 were rejected under 35 U.S.C. §103(a) as being unpatentable over Schiff and Hawkins et al., further in view of Peers-Trevarton. Claims 16 and 17 embody the subject matter of claim 7 therein, from which they depend, and therefore the above arguments regarding the teachings of Schiff and Hawkins et al. are applicable to claims 16 and 17.

As described at column 3, the connector portion in that reference is referred to as a "neck" 22, and is explicitly stated to be fabricated from molded epoxy resin (column 3, line 42). This is also apparent from the type of hatching for the element 40 shown in the sectional views, which clearly indicates a plastic-like material, or at least a non-metallic material. Neither the Peers-Trevarton reference, nor any other reference of record, provides any teachings of guidance as to how the locking mechanism disclosed in Peers-Trevarton could be used in the context of a metallic header. Since the locking mechanism disclosed in the Peers-Trevarton reference is intended for use in a header composed of apoxy resin (i.e., insulating material), Peers-Trevarton did not have to be concerned with insulating problems, however, those problems are paramount in designing and arranging components in a metallic header, as discussed above. This is yet another example of why those of ordinary skill in the field of pacemaker design recognize that one cannot simply "lift" teachings from a patent relating to a pacemaker with a resin header, and use those teachings without modification in a pacemaker having a metallic header.

Therefore, even if the device disclosed in the Schiff reference were modified in accordance with the teachings of Peers-Trevarton, the subject matter of claim 7 still would not result from which claims 16 and 17 depend. Claims 16 and 17, therefore would not have been obvious to a person of ordinary skill in the art under the provisions of 35 U.S.C. §103(a) based on the teachings of Schiff, Hawkins et al. and Peers-Trevarton.

CONCLUSION:

For the foregoing reasons, Appellants respectfully submit the Examiner is in error in law and in fact in rejecting claims 7-13, 16 and 17. Reversal of these rejections is proper, and the same is respectfully requested.

This Appeal Brief is accompanied by a check for the requisite fee in the amount of $330.00.

Submitted by,

Steven H. Noll (Reg. 28,982)

SCHIFF, HARDIN LLP
CUSTOMER NO. 26574
Patent Department
6600 Sears Tower
233 South Wacker Drive
Chicago, Illinois 60606
Telephone: 312/258-5790
Attorneys for Appellants.

CERTIFICATE OF MAILING

I hereby certify that an original and two copies of this correspondence are being deposited with the United States Postal Service as First Class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on May 10, 2004.

Steven H. Noll

STEVEN H. NOLL

APPENDIX "A"

7. A pacemaker comprising:

a metallic housing having a first wall with a first opening therein and a second wall with a second opening therein;

a metallic tubular member having a first tube end disposed in and attached to said first opening and an opposite second tube end disposed in and attached to said second opening, said tubular member being substantially continuous between said first tube end and said second tube end; and

a plurality of interior components disposed within said tubular member adapted to make electrical contact with contact surfaces of a contact plug adapted for insertion into said tubular member.

8. A pacemaker as claimed in claim 7 wherein said first and second tube ends are respectively bonded to said metallic housing at said first and second openings.

9. A pacemaker as claimed in claim 7 wherein said first and second tube ends are respectively welded to said metallic housing at said first and second openings.

10. A pacemaker as claimed in claim 7 wherein said metallic tubular member has at least one lateral opening therein, and having a contact surface disposed in said opening for establishing electrical contact between the interior of said metallic tubular member and an exterior of said metallic tubular member, said

contact surface being electrically connected to at least one of said interior components.

11. A pacemaker as claimed in claim 10 further comprising an insulating ceramic plug disposed in and closing said lateral opening, said ceramic plug being mechanically attached in said lateral opening and holding said contact surface in said opening.

12. A pacemaker as claimed in claim 11 wherein said ceramic plug is soldered in said lateral opening.

13. A pacemaker as claimed in claim 11 wherein said ceramic plug is bonded in said lateral opening.

16. A pacemaker as claimed in claim 7 further comprising a locking arrangement disposed at said second tube end, and accessible from said second tube end, adapted for locking an end of an electrode lead in said metallic tubular member.

17. A pacemaker as claimed in claim 16 wherein said locking arrangement is at least partially removable from said metallic tubular member to allow access to said end of said electrode lead.

Fig. 1

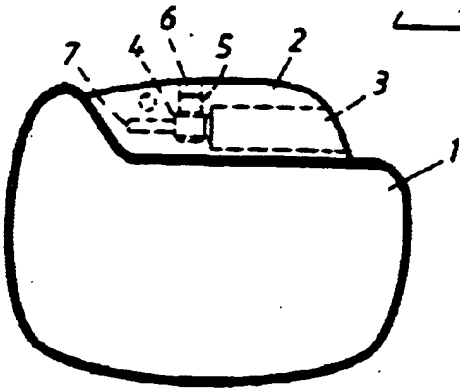

Fig. 2

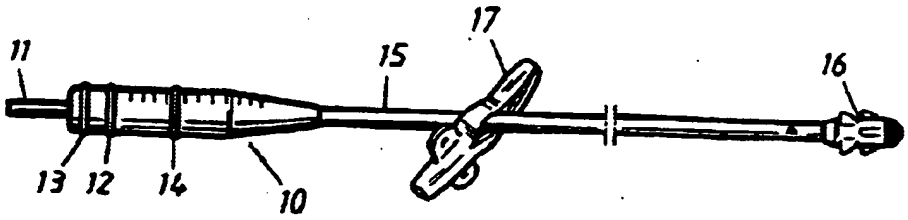

Fig.3

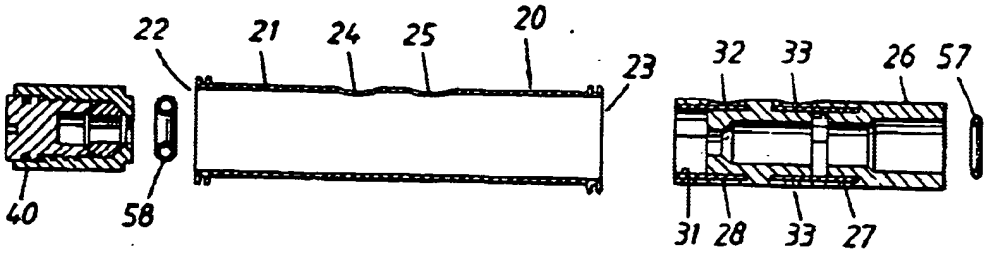

Fig.4

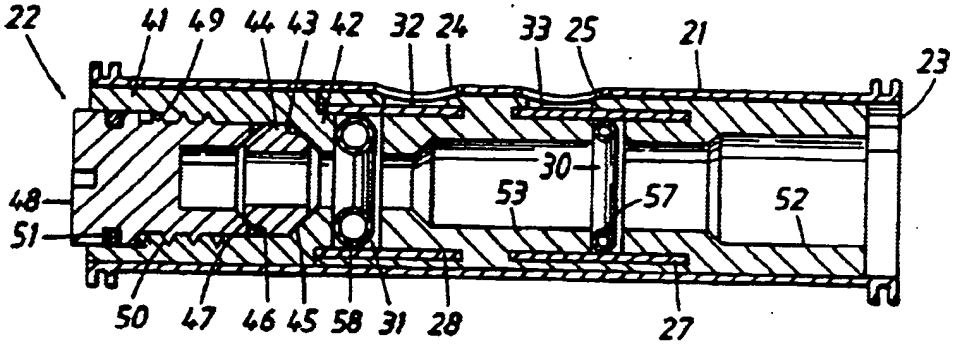

Fig.5